

Post text table 5.1-9b (Page 1 of 6)
 Incidence density rate per 1000 month of monitoring for skin infection and non skin infections
 (AD: Adult population)

Infection type Preferred term		ASM 1% DB (N=543)	Vehicle DB (N=444)	Relative risk	95% CI	p-value	Total ASM 1% (N=1447)	(month follow-up=8065)
		(month follow-up=2819)	(month follow-up=2154)					
-Occurrences of skin infection								
-Total		72 25.5	44 20.4	1.250	(0.86,1.83)	0.243	234	29.0
Bacterial								
-Total		32 11.4	18 8.4	1.358	(0.77,2.47)	0.299	92	11.4
ABSCESS		1 0.4	0				2	0.2
ANAEROBIC PYODERMA NOS		0	0				1	0.1
BLEPHARITIS		1 0.4	2 0.9	0.382	(0.02,3.99)	0.432	3	0.4
CELLULITIS		1 0.4	1 0.5	0.764	(0.03,19.3)	0.849	3	0.4
DERMATITIS INFECTED		0	1 0.5				3	0.4
ECZEMA IMPETIGINOUS		0	0				2	0.2
ERYSIPelas		1 0.4	0				3	0.4
FOLLICULITIS		5 1.8	2 0.9	1.910	(0.41,13.3)	0.439	20	2.5
FURUNCLE		3 1.1	1 0.5	2.292	(0.29,46.3)	0.473	8	1.0
GROIN ABSCESS		0	0				1	0.1
IMPETIGO		2 0.7	2 0.9	0.764	(0.09,6.37)	0.788	20	2.5
PARONYCHIA		1 0.4	0				2	0.2
POST PROCEDURAL SITE WOUND INFECTION		1 0.4	0				1	0.1
SKIN AND SUBCUTANEOUS TISSUE ABSCESS		0	0				1	0.1
NOS								
SKIN BACTERIAL INFECTION		13 4.6	2 0.9	4.967	(1.37,31.8)	0.035	16	2.0
STYE		0	4 1.9				0	
SUBCUTANEOUS ABSCESS		1 0.4	0				1	0.1
SUPERINFECTION		0	1 0.5				2	0.2
TINEA VERSICOLOUR		1 0.4	0				2	0.2
WOUND INFECTION		1 0.4	2 0.9	0.382	(0.02,3.99)	0.432	1	0.1

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	(month follow-up=2819)	(month follow-up=2154)						(month follow-up=8065)	
Fungal									
-Total	6	2.1	5	2.3	0.917	(0.28,3.18)	0.886	15	1.9
BODY TINEA	1	0.4	1	0.5	0.764	(0.03,19.3)	0.849	2	0.2
DERMATOPHYTOSIS	1	0.4	0					1	0.1
GENITAL INFECTION FUNGAL	1	0.4	0					1	0.1
NAIL INFECTION	1	0.4	0					3	0.4
NAIL TINEA	0		0					1	0.1
ORAL CANDIDIASIS	1	0.4	0					1	0.1
SKIN FUNGAL INFECTION	1	0.4	1	0.5	0.764	(0.03,19.3)	0.849	2	0.2
TINEA CRURIS	0		1	0.5				1	0.1
TINEA PEDIS	0		2	0.9				3	0.4

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	(month follow-up=2819)	(month follow-up=2154)				(month follow-up=8065)
Parasitic						
-Total	0	0				1 0.1
SCABIES INFESTATION	0	0				1 0.1
Skin infection non specified						
-Total	3 1.1	0				18 2.2
APPLICATION SITE INFECTION	0	0				2 0.2
EYELID INFECTION	0	0				2 0.2
GENITAL INFECTION	0	0				1 0.1
LOCALISED INFECTION	0	0				1 0.1
RASH PUSTULAR	1 0.4	0				5 0.6
SKIN INFECTION	2 0.7	0				7 0.9
Viral						
-Total	31 11.0	21 9.7	1.128	(0.65,1.99)	0.670	108 13.4
CHICKENPOX	3 1.1	0				5 0.6
CONDYLOMA ACUMINATUM	0	0				1 0.1
HERPES SIMPLEX	25 8.9	17 7.9	1.124	(0.61,2.12)	0.711	90 11.2
HERPES SIMPLEX DERMATITIS	0	2 0.9				1 0.1
HERPES SIMPLEX OPHTHALMIC	0	0				1 0.1
HERPES ZOSTER	2 0.7	1 0.5	1.528	(0.15,32.9)	0.729	4 0.5
PITYRIASIS ROSEA	1 0.4	1 0.5	0.764	(0.03,19.3)	0.849	1 0.1
SKIN PAPILLOMA	0	0				5 0.6

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	(month follow-up=2819)	(month follow-up=2154)				(month follow-up=8065)
Non skin infection						
-Total	305	108	1.280	(1.07,1.54)	0.008	754 93.5
APPENDICITIS	0	0				1 0.1
BLADDER INFECTION NOS	1	0.4				1 0.1
BORRELIA INFECTION	0	1 0.5				0
BRONCHIAL INFECTION	0	0				1 0.1
BRONCHITIS	7 2.5	6 2.8	0.891	(0.30,2.77)	0.836	21 2.6
CANDIDIASIS	0	0				1 0.1
CATHETER RELATED INFECTION	2 0.7	0				2 0.2
CHLAMYDIAL INFECTION	0	1 0.5				0
CONJUNCTIVITIS	3 1.1	0				5 0.6
CYSTITIS	3 1.1	3 1.4	0.764	(0.14,4.13)	0.742	9 1.1
CYSTITIS NOS	1 0.4	0				1 0.1
DENTAL CAVITIES	1 0.4	0				1 0.1
EAR INFECTION	3 1.1	1 0.5	2.292	(0.29,46.3)	0.473	12 1.5
FUNGAL INFECTION	1 0.4	0				1 0.1
GASTROENTERITIS	7 2.5	7 3.2	0.764	(0.26,2.23)	0.615	13 1.6
GASTROENTERITIS VIRAL	6 2.1	0				7 0.9
GASTROINTESTINAL CANDIDIASIS	0	0				1 0.1
GASTROINTESTINAL INFECTION	2 0.7	4 1.9	0.382	(0.05,1.96)	0.267	7 0.9
GINGIVAL ABSCESS	0	0				1 0.1
HERPES SIMPLEX OTITIS EXTERNA	0	1 0.5				0
HERPES VIRUS INFECTION	1 0.4	2 0.9	0.382	(0.02,3.99)	0.432	7 0.9
HORDEOLUM	0	0				1 0.1
INFECTION	3 1.1	0				3 0.4
INFECTION PROTOZOAL	0	0				1 0.1

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INFECTIVE MYOSITIS	0	0				1 0.1
INFLUENZA	37 13.1	24 11.1	1.178	(0.71,1.99)	0.532	82 10.2
JOINT ABSCESS	0	0				1 0.1
KERATITIS HERPETIC	0	0				1 0.1
KIDNEY INFECTION	0	1 0.5				0
LABYRINTHITIS NOS	0	0				1 0.1
LARYNGITIS	1 0.4	0				1 0.1
LICE INFESTATION	1 0.4	0				1 0.1
LOWER RESPIRATORY TRACT INFECTION	0	0				1 0.1
NASOPHARYNGITIS	113 40.1	78 36.2	1.107	(0.83,1.48)	0.490	322 39.9
OTITIS EXTERNA	5 1.8	2 0.9	1.910	(0.41,13.3)	0.439	5 0.6
OTITIS MEDIA	4 1.4	1 0.5	3.056	(0.45,59.8)	0.318	6 0.7
PAROTITIS	1 0.4	0				2 0.2
PERIORBITAL CELLULITIS	0	0				2 0.2
PERITONSILLAR ABSCESS NOS	1 0.4	0				1 0.1
PHARYNGITIS	5 1.8	2 0.9	1.910	(0.41,13.3)	0.439	20 2.5
PHARYNGITIS STREPTOCOCCAL	1 0.4	1 0.5	0.764	(0.03,19.3)	0.849	3 0.4
PHARYNGOTONSILLITIS	0	1 0.5				2 0.2
PNEUMONIA	2 0.7	2 0.9	0.764	(0.09,6.37)	0.788	4 0.5
POSTOPERATIVE INFECTION	1 0.4	0				1 0.1
PULPITIS DENTAL	1 0.4	0				1 0.1
PYELONEPHRITIS	1 0.4	0				2 0.2
RESPIRATORY TRACT INFECTION	1 0.4	1 0.5	0.764	(0.03,19.3)	0.849	5 0.6
RHINITIS	15 5.3	6 2.8	1.910	(0.78,5.36)	0.180	32 4.0
RHINITIS INFECTIVE	0	0				1 0.1
SINUSITIS	15 5.3	9 4.2	1.274	(0.57,3.03)	0.566	39 4.8

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	(month follow-up=2819)	(month follow-up=2154)					
TONSILLITIS	6	2.1	1	0.5	4.585 (0.78,86.6)	0.159	13 1.6
TOOTH ABSCESS	1	0.4	1	0.5	0.764 (0.03,19.3)	0.849	1 0.1
TOOTH INFECTION	1	0.4	0				6 0.7
TRACHEOBRONCHITIS	0		0				1 0.1
TRICHOMONIASIS	1	0.4	0				1 0.1
TUBERCULOSIS	0		0				1 0.1
UPPER RESPIRATORY TRACT INFECTION	32	11.4	19	8.8	1.287 (0.74,2.31)	0.384	53 6.6
URINARY TRACT INFECTION	11	3.9	3	1.4	2.802 (0.87,12.4)	0.114	21 2.6
VAGINAL CANDIDIASIS	1	0.4	0				3 0.4
VAGINAL INFECTION	0		0				2 0.2
VAGINAL MYCOSIS	1	0.4	0				2 0.2
VAGINITIS	0		1	0.5			0
VAGINITIS BACTERIAL	0		0				2 0.2
VAGINITIS BACTERIAL NOS	0		0				1 0.1
VAGINITIS GARDNERELLA	0		0				1 0.1
VAGINOSIS FUNGAL NOS	1	0.4	0				1 0.1
VIRAL INFECTON	0		2	0.9			4 0.5
VIRAL PHARYNGITIS	2	0.7	0				3 0.4
VIRAL UPPER RESPIRATORY TRACT	2	0.7	0				3 0.4
INFECTION							
VULVOVAGINITIS	0		1	0.5			1 0.1